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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,727	09/29/2006	Yasushi Itou	1027550-000895	9393

21839 7590 02/02/2009
BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

OSINSKI, BRADLEY JAMES

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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02/02/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/594,727	Applicant(s) ITOU ET AL.	
	Examiner BRADLEY J. OSINSKI	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoste (6,508,806) in view of Bazaral (4,925,448) and Van Es (5,501,341).

a. Regarding claims 1-3, Hoste discloses an angiographic catheter with a lumen and stainless steel metal reinforcement embedded within the wall to vary catheter pitch (Col.3 lines 5-14) and the length of the catheter being 80-125 cm for coronary angioplasty. The catheter thus has distal and proximal portions of 40-62.5 cm in length. Additionally, disclosed is a connector part fixed to the proximal portion of the catheter body. While Hoste substantially discloses the invention as claimed, it does not disclose the states in which the catheter is held in a packaging. However, Bazaral discloses a proximal portion held in a curved state by the compartment and is covered by a plastic impermeable to microorganisms and particles. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to enclose the proximal half of Hoste in a plastic compartment/tray as disclosed by Bazaral to

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keep the distal portion protected from microorganisms and particles while the proximal portion is being attached to the appropriate machines. Van Es discloses the distal half held on a card in its natural state so that the catheter is not damaged as it is withdrawn from the plastic/tray. It would have been obvious to one of ordinary skill in the art to hold the distal end in its natural state on a card so that as the card is withdrawn, the distal end is not damaged.

b. Regarding claims 4 and 6, as can be seen in figure 1 of Hoste, the distal end has a curved shape in its natural state.

c. Regarding claims 5 and 7-9, While Hoste substantially discloses the invention as claimed, it does not disclose the catheter spanning two trays separately integrated with each other. However, Bazaral discloses a catheter spanning two trays as in figure 1 integrated into one package, but separated by different plastic films (figure 7). Therefore, it would have been obvious to one of ordinary skill in the art to use the trays of Bazaral so that the distal and proximal sections remain separate so that the other section remains protected microorganisms and particles while the other section is being setup/used.

d. Regarding claim 10, see claim 1 above, the package of Bazaral has a bottom and upstanding walls as can be seen in figures 2 and 4.

e. Regarding claims 11 and 12, the different sections of Bazarar comprise a plurality of separate trays (separated by the walls, such as 102 and 112) that are back to back with each other and have cutouts (such as 113, 103 and 107).

Response to Arguments

2. Applicant's arguments, see Applicant Arguments/Remarks, filed 10/23/2008, with respect to claim 1 have been fully considered and are persuasive. The rejection under 102 of claim 1 has been withdrawn.

3. Applicant's arguments filed 10/23/2008 have been fully considered but they are not persuasive.

f. Applicant argues that the package of Bazaral would render a catheter having a wire reinforcement unusable because it would result in plastic deformation of the wires at the distal end. Applicant quotes pages 2 and 3 of the application as evidence. However, Applicant specifically requires the distal portion of the catheter having a curved shape in claim 4. Furthermore, a curve is desirable in instances where a curve would assist the device in reaching a site, such as in PTCA procedures (Col.1 lines 11-17 of Hoste).

g. Applicant argues enclosing Hoste's device in the device of Bazaral would not afford the distal end protection while the proximal end is being attached to the appropriate devices. However, figures 6 and 7 clearly indicate different trays for the proximal and distal ends such that as the proximal end is unwrapped and attached to devices, the distal end is protected until the device is ready for use.

h. Applicant argues that the office action fails to explain what a curled state has to do with protection from contamination. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

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teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the references are combined for contamination prevention of the device of Hoste, which has a curled state.

i. Applicant argues Van Es does not disclose holding the distal half of a catheter on a card in its natural state. However, if the device has a naturally curved distal end, it does.

j. Applicant argues that there is nothing to suggest that the tray-type package of Bazaral and the card-type package of Van Es are not integratable. However, reference is made to both Forney (5,165,540) and Foos (5,322,163) which have both tray and card like properties integrated together.

k. Applicant argues that the office action fails to explain how the combination would have resulted in the distal portion of the catheter held in a natural state with the remaining proximal side held in a curled state. Examiner is unclear how enclosing the proximal end of the device as taught by Bazaral would not result in a curved proximal portion, as such is clearly indicated in figures 1 and 7 and how enclosing the distal end of the device in Van Es would not result in the distal portion being held in a natural state as such is clearly indicated in figures 1 and 2.

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I. Applicant argues the Examiner did not address the curvature diameter of 10 to 50 cm, only the length. As the proximal section is 40-62.5 cm long and Bazaral shows the proximal section in a half circle to full circle (figures 1 and 7), the outside circumference of the circle is known. Using pi, the curvature diameter may be calculated. If the proximal section was rolled in a full circle, the curvature diameter would be 13-20 cm and if the proximal section was rolled in a half circle, the curvature of diameter would be 26-40 cm.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767